UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,976	08/17/2001	Paul V. Haydock	018048-0011100US	7225

20350 7590 05/24/2002

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	PAPER NUMBER
1637	5

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,976	HAYDOCK ET AL.	
	Examiner	Art Unit	
	Cynthia B Wilder	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☒ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority for 60/106,857 filed 11/03/1998 under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 112 second paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

3. Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 36 is indefinite at the recitation of NASBA because abbreviations often have more than one meaning in the art. It is suggested inserting the full name as supported in the specification as originally filed.

(b) Claim 37 is indefinite at the recitation of TCA because abbreviations often have more than one meaning in the art. It is suggested inserting the full name as recited in the specification as originally filed.

Trademark or Trade Name

4. Claims 13, 17, and 43 contains the trademark/trade name GEL SLICK. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a non-stick coating material and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 15-17, 23-26, 28-34 and 38-44, 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Stavrianopoulos et al. (US 4,994,373, Feb. 19, 1991). Regarding claims 15-17, and

41-43, Stavrianopoulos et al. teach a method for detecting a target analyte, the method comprising (a) contacting a test sample with a solid support which comprises a capture reagent that binds to the target analyte, wherein the solid support is coated with a non-stick coating material prior to contacting the sample; (b) contacting the solid support with a signal reagent which binds to the target analyte and (c) determining whether the test sample contains the target analyte by detecting the presence of a signal reagent immobilized on the solid support (col. 8, lines 10-56). Stavrianopoulos et al. further teach wherein the non-stick coating is a silanizing agent consisting of silane (col. 8, lines 23-27).

Regarding claims 23-25, 44, Stavrianopoulos et al. teach wherein the method comprise several washing steps and wherein the solid support is glass (col. 7, lines 37-43).

Regarding claim 26, Stavrianopoulos et al. teach wherein the capture reagent covalently attaches to the solid support (col. 7, lines 37-43).

Regarding claims 28-30, Stavrianopoulos et al. teach wherein the capture reagent comprises a tag which binds to a tag binder attached to the solid support wherein the tag is biotin and the tag binder is avidin or streptavidin or an antibody that binds to biotin (col. 10, lines 25-52).

Regarding claims 31-32, 38, 46, and 47, Stavrianopoulos et al. teach wherein the target analyte comprises a polynucleotide and the capture reagent comprises and oligonucleotide which hybridizes to the polynucleotide and wherein the polynucleotide is DNA ((col. 7, lines 41-45).

Regarding claims 33, 34, 39, 40, Stavrianopoulos et al. teach wherein the signal reagent comprises a detectable label attached to an antibody which specifically binds to double stranded

nucleic acid (col. 10, lines 35-52). Therefore, the claimed invention of claims 15-17, 23-26, 28-34 and 38-47 are anticipated by the reference of Stavrianopoulos et al.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 18-22, 27, 37 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky et al. (US 5, 229, 297, July 20, 1993) in view of Douglas (US 5,556,748, Sept. 17, 1996) and further in view of Ness et al. (Nucleic acids Research, October 1991). Regarding claims 1-14, 18-22, 27 and 37, Schnipelsky et al. teach a method of reducing cross-contamination of an assay reagent solution, the method comprising contacting a solid support with a first reagent solution,

removing the solid support from contact with the first reagent, contacting the solid support with a second reagent, removing the solid support and contacting the solid support with one or more intermediate reagents solution, wherein the intermediate reagent solution is a wash solution (col. 10, lines 13-46). The reference further teaches wherein the solid support is a glass bead (col. 12, lines 39-43). Schnipelsky et al. teach wherein the reagents are placed into containers (cuvettes) (col. 9, lines 63-66). The reference also teaches wherein the solid support is comprise of a capture reagent noncovalently attached to the solid support wherein the capture reagent is capable of specifically binding to a target analyte and substrate which produces a detectable product when contacted with the enzyme (col. 10, lines 19-30 and col. 12, lines 39-43). The method of Schnipelsky et al. differs from the instant invention in that Schnipelsky et al. do not teach wherein the solid support is coated with a non-stick material selected from the group consisting of silane, dimethylchlorosilane and GEL STICK, prior to contacting the solid support with the first reagent.. The reference also does not teach wherein a denaturant such as a chaotropic agent or a detergent is utilized as a first reagent.

Douglas et al. teach a method of detecting a target analyte wherein the solid support is coated with a non-stick material consisting of of silane, a capture probe covalently attached on the support and a substrate which produces a detectable product when contacted with an enzyme linked to a signal reagent (col. 2, lines 23-37). Douglas further discloses wherein the solid support consist of wells (col. 2, lines 29-30). The method of Douglas et al. differs from the instant invention in that Douglas et al. do not teach wherein the method comprises a first reagent comprising a denaturant selected from the group consisting of a chaotropic agent or a detergent. Ness et al. teach a method

of detecting an analyte in a sample comprising contacting the sample with a denaturant consisting of a chaotropic agent, sodium thiocyanate (page 5144, col. 1, lines 4-5, see also abstract). Ness et al. further teach that the denaturant is useful for lysing the cells or organism of interest, inhibiting nucleases and proteases, and providing adequate binding stringency without chemically altering the target analyte (page 5143, col. 1, second paragraph). Therefore, in view of the foregoing one of ordinary skill in the art would have been motivated to utilize a chaotropic solution as the first reagent in the method of Schnipelsky et al. and Douglas et al. for the expected benefits of denaturing the target cells of interest in a sufficient manner without chemically altering the target as taught Ness et al. Additionally one of ordinary skill in the art would have been motivated to utilized a solid support coated with a non-stick coating for the obvious benefit of preventing residual contamination on the solid support.

8. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stavrianopoulos et al. in view of Stapleton (US 5,436,129, July 25, 1995). Stavrianopoulos et al. teach a method of detecting a target analyte in a sample. the method comprising contacting a sample with a solid support with comprises a capture reagent that binds to the target analyte, wherein the solid support is coated with a non-stick coating material prior to the contacting the sample with the support; contacting the the solid support with a signal reagent which binds to the target analyte; and determining whether the sample contains the target analyte by detecting the presence of signal reagent immobilized on the solid support wherein the target analyte is a polynucleotide (col. 8, lines 20-6). The reference does not teach wherein the polynucleotide is amplified prior to the contacting

of the sample with the capture agent. The reference of Stavrianopoulos et al do not expressly teach that wherein the polynucleotide is amplified prior to contacting the sample with the capture reagent. However, it is well known in the art that methods of amplification are routinely used to increase the sample size prior to analysis. For example, in a general teaching of analysis of nucleic acid sequences, Stapleton defines amplification as a means to biochemically increase the target nucleic acid mass for subsequent analyses (col. 20, lines 60-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have been motivated to perform amplification prior to analysis for the obvious benefit of increasing the amount of starting material for analysis as suggested by Stapleton.

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

May 9, 2002

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/13/02